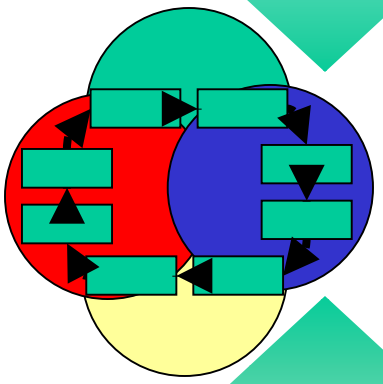
Protocol Representation Special Interest Group
July 19, 2004

Agenda

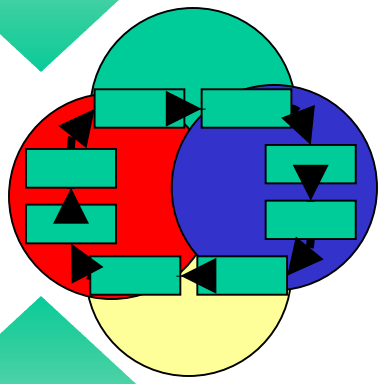
- Goals for today
  - Review the vision statement from the face to face meeting
  - Discuss the scope of the SIG
  - Examine possible work statements to achieve those goals
- Deliverables
  - A draft vision statement
  - Homework for scope and use cases
  - Comment on possible statements of work
- SOW process: White paper(s) from this sig
  - Review of existing stake holders
  - Design considerations
- Next teleconference call:
  - August 3, 1:00 EDT

Desiderata

Standards-Driven Development



caBIG compliant, open-source, integrated, modular, software applications that are USED



User-Driven Development

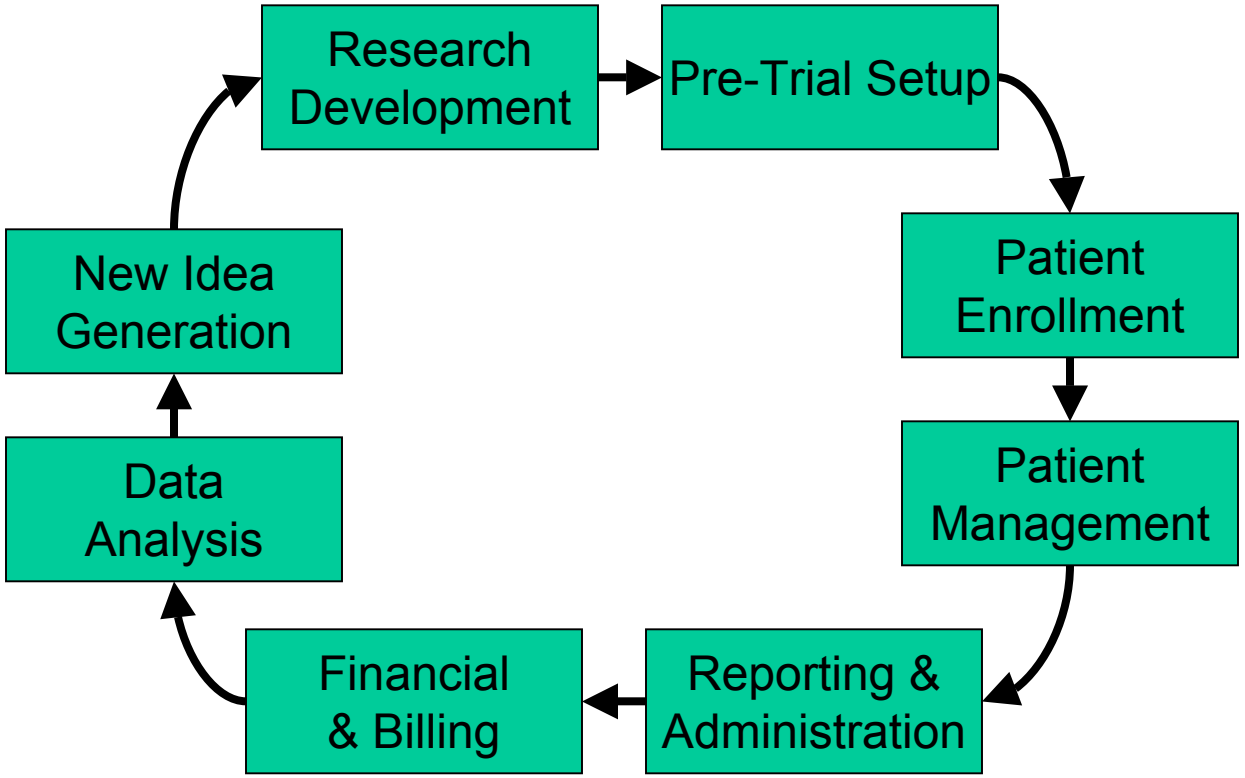
Vision

- To *define* a computable protocol representation that supports the entire life-cycle of clinical trials protocol, and *develop tools* that use these protocol representations. These tools should be standards-based, caBIG compliant and assist users in creating, maintaining, and sharing clinical trials information.
- The clinical trials protocol representation will serve as a *foundation* for caBIG modules that support *all phases* of the clinical trials life cycle, (including protocol authoring) and be developed to meet user needs and requirements.
- At every stage, we will *evaluate* and *test* our work

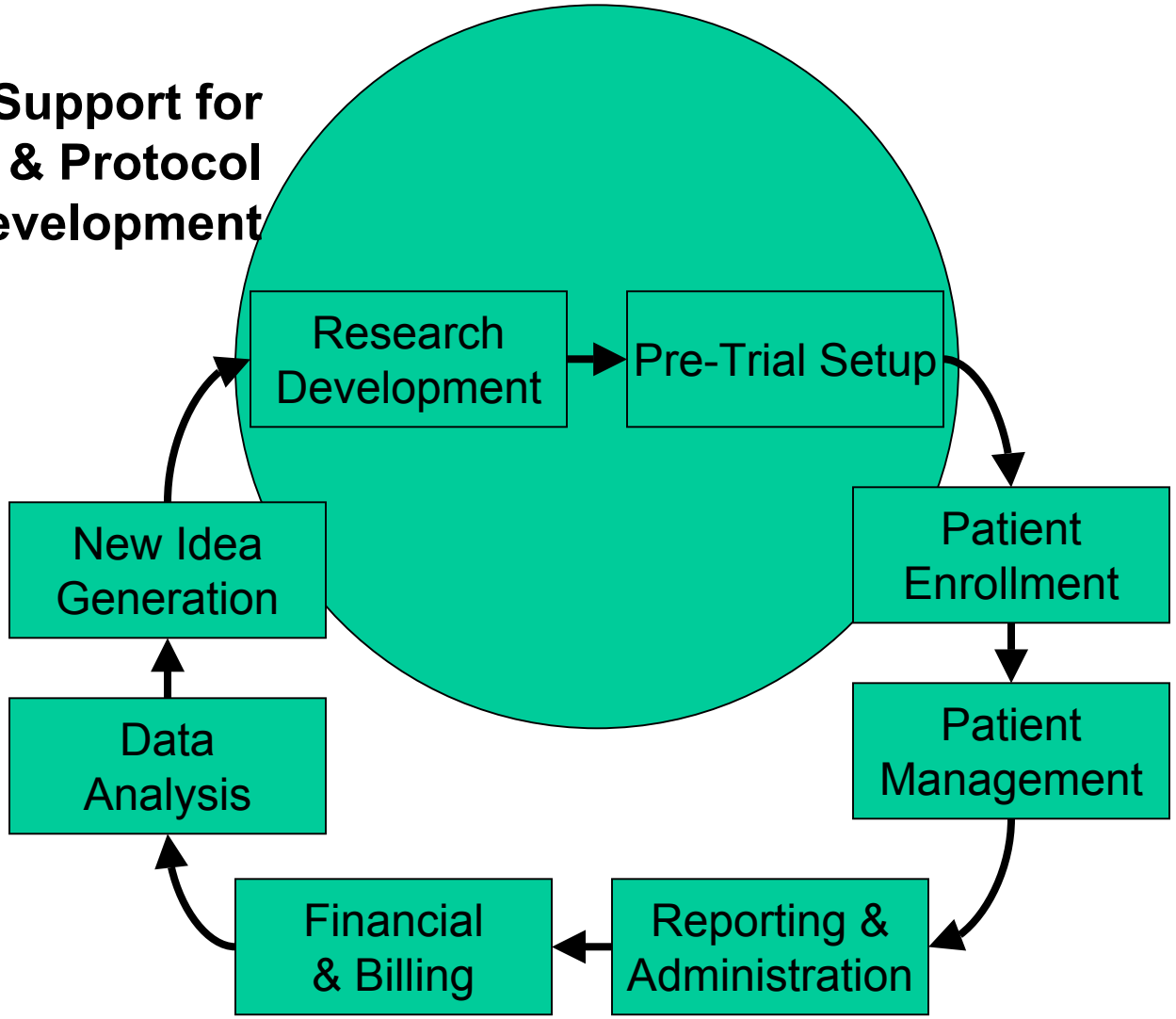
SIG worktasks

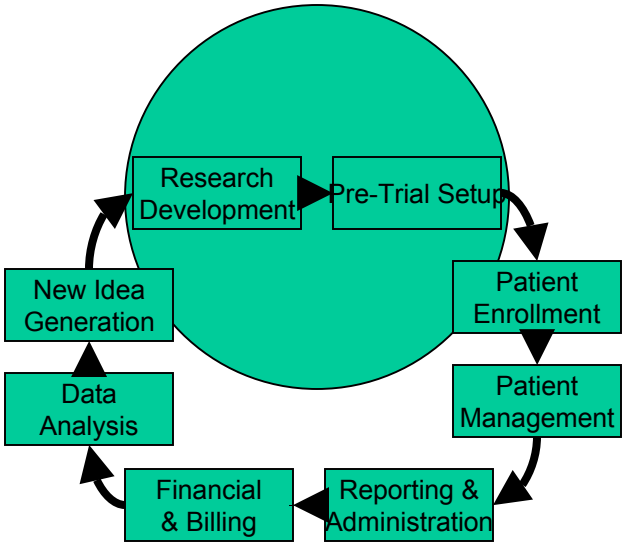
- Vision and Scope
  - Complete vision and scope document
- Interact with other protocol representation groups (ongoing)
  - CTEP/CDISC
  - HL7
- Use case development and user requirements
  - Begin the process of identifying use cases for the life cycle
  - Develop complete protocol registration use case (transferring paper-based description of protocol into clinical trial management system)
  - Develop complete summary 4 use case
- Develop representational constructs based on use cases

Clinical Trial Life-Cycle



Support for Research & Protocol Development





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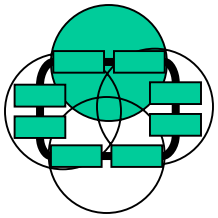
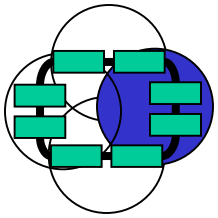
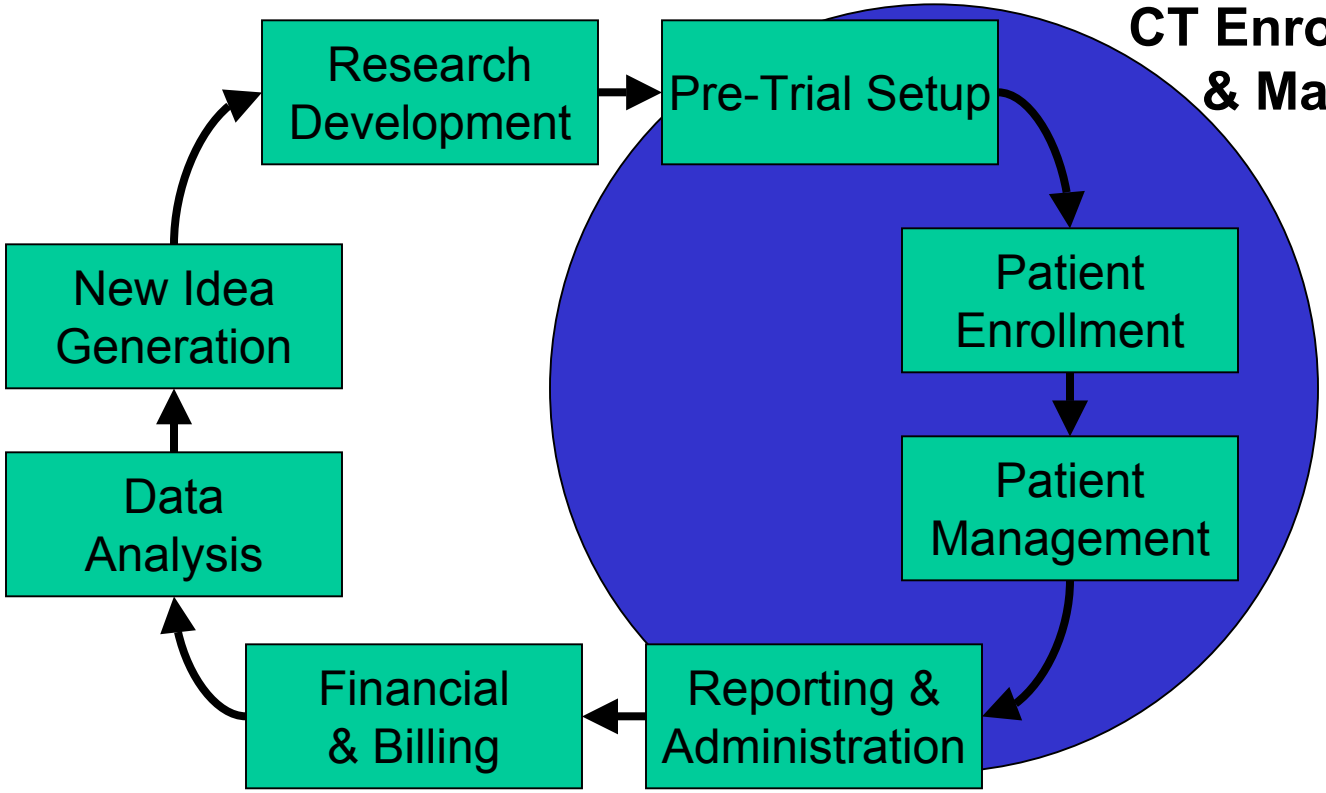
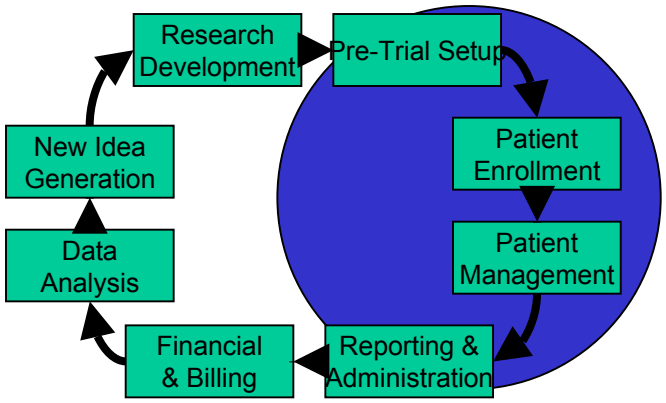


- Principal Investigator
  - Authors CT protocol using tools to construct document and schema
    - *Authoring environment for PI*
  - Submits protocol and proposal for scientific review
    - *Machine and human readable submission*
- Clinical Research Coordinator
  - Registers CT protocol into management application
    - *Authoring environment for CRC*
  - Coordinates IRB submission and review
- Pharmaceutical company
  - Development of new compounds and requires submission to FDA, etc.
    - Authoring environment for Pharma (LOI (phase 1,2), concept (phase 3) with CTEP requirements
- ?unique protocol identifier?
- PI registry
- Government protocol registries



Support for CT Enrollment & Management





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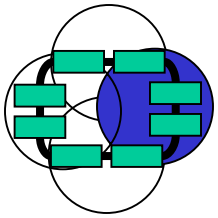
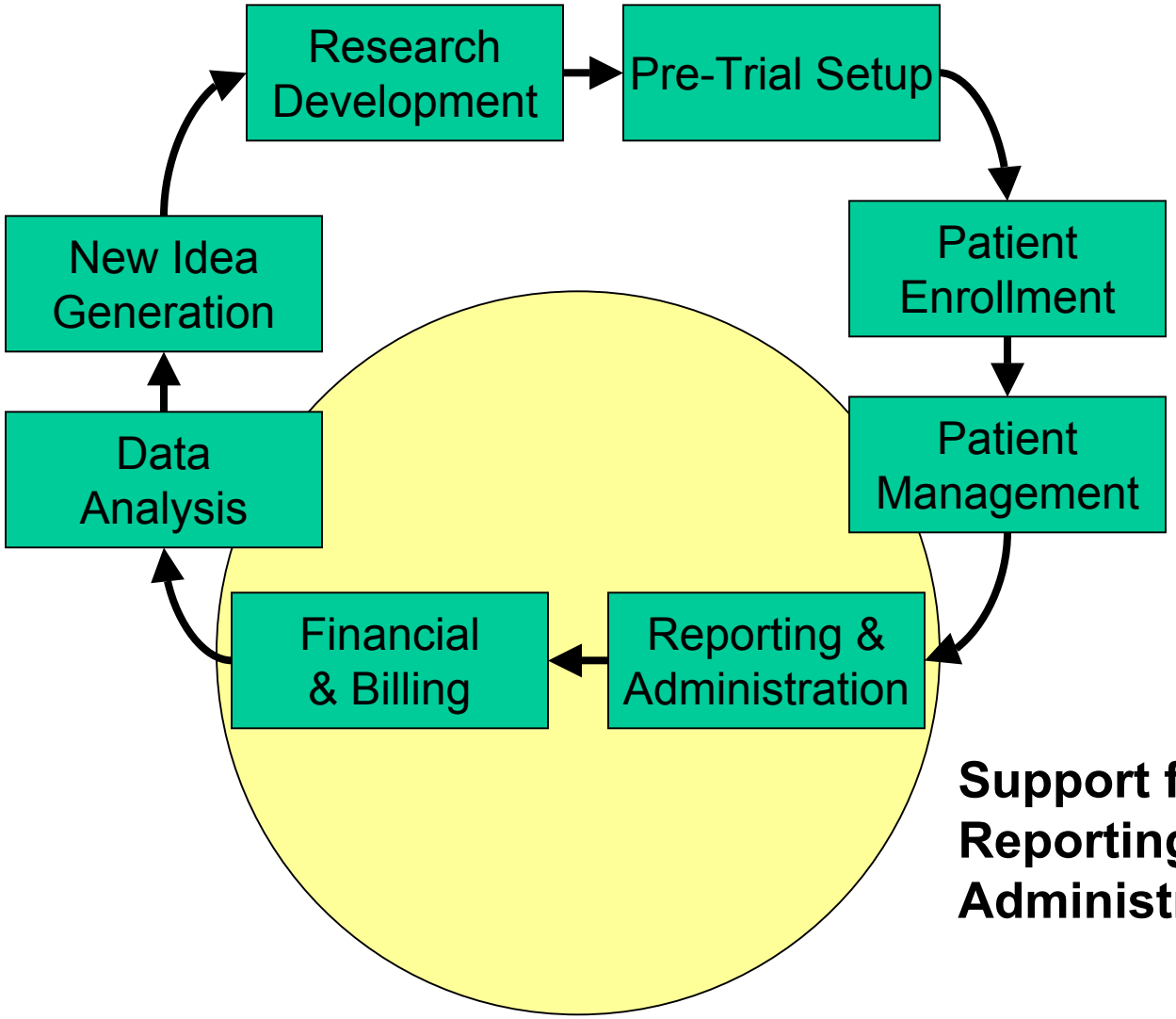
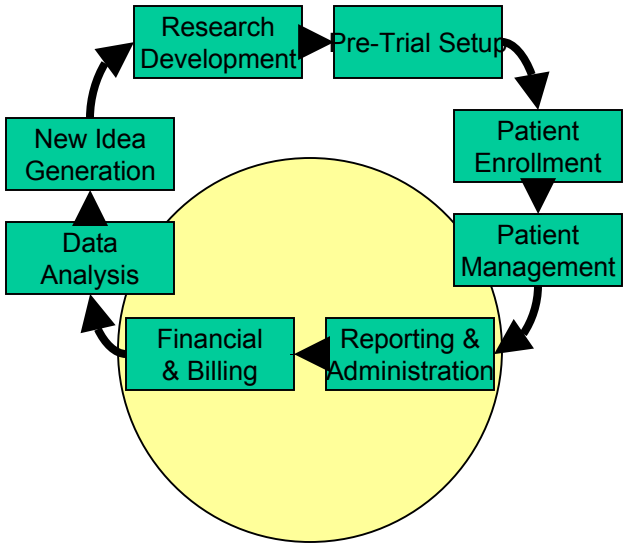


- Patient
  - Identifies trials and eligibility
- Oncologist
  - Matches trial with patient
- Clinical Research Coordinator
  - Determines patient eligibility
  - Tracks patient through treatment cycle
  - Reports adverse events and complications
  - Reports patient outcomes and progression
  - Manages multiple hospital and information systems
- Data registrar
- Sharing information between institutions
  - Doug Stahl (AACI cancer centers)
  - Cooperative groups



Support for CT Reporting & Administration



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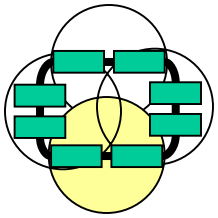
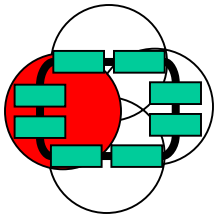
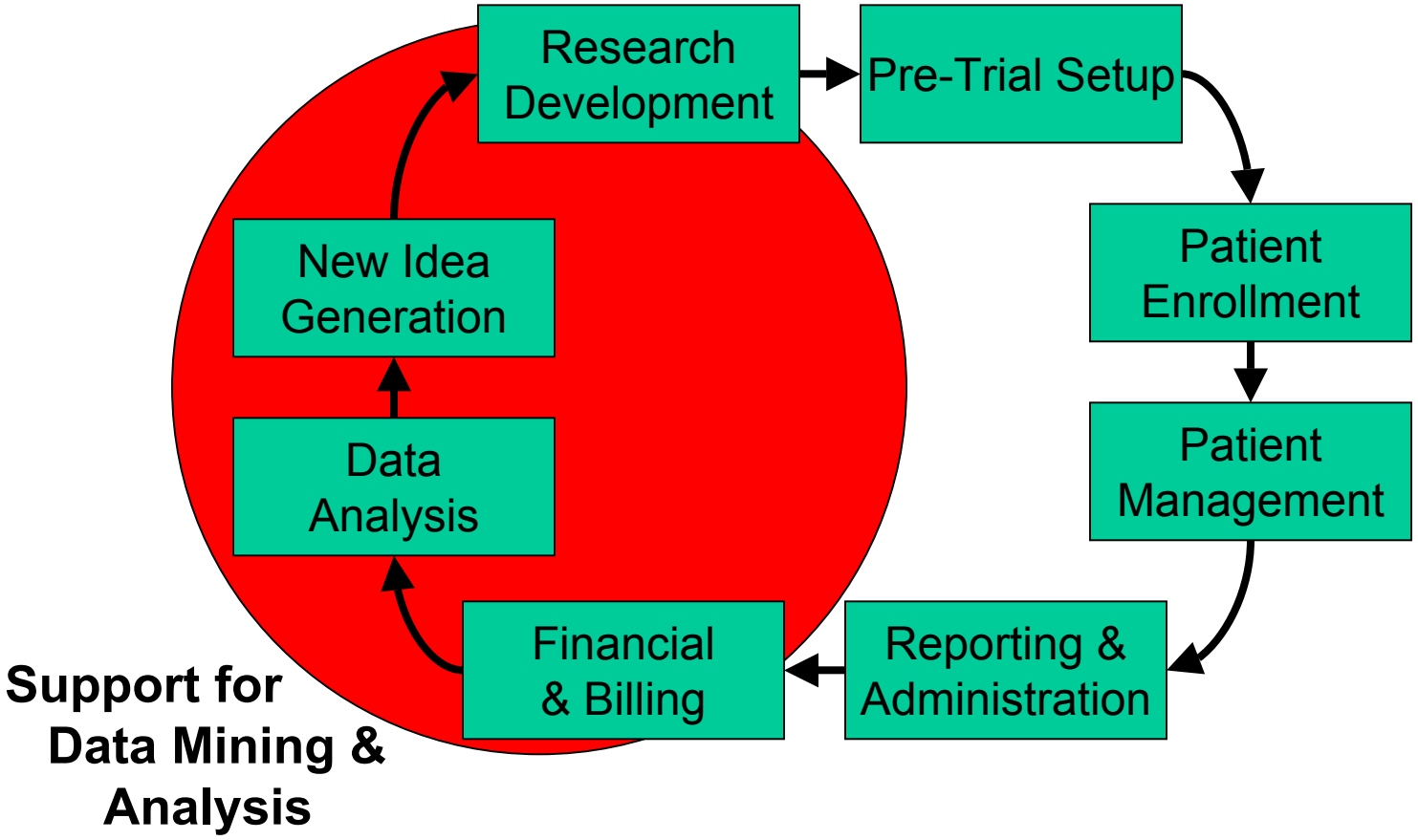
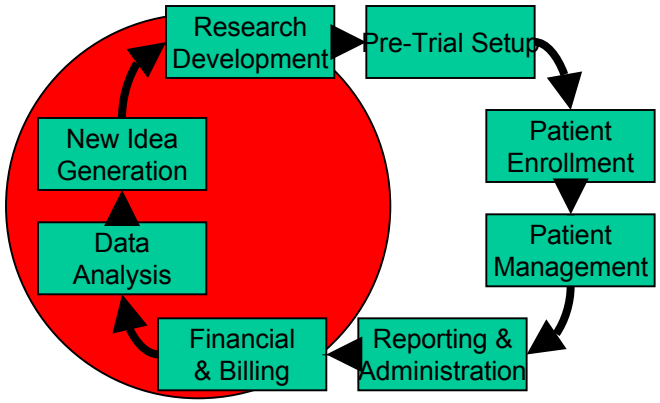


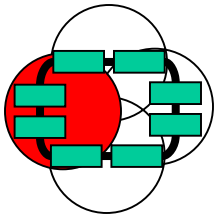
- Clinical Research Coordinator
  - Reports summary 4 statistics
  - CTMS reporting
    - I&D
    - Patient-level reporting (sponsors, and regulators)
  - Reports adverse events
  - Report medical errors
- Financial systems
  - Identifies standard of care vs. clinical trial activities
- Patients
  - Status of the clinical trials
- Administrators
  - Identify status, accruals etc of a protocol




Research Development
Pre-Trial Setup
Patient Enrollment
Patient Management
Reporting & Administration
Financial & Billing
Data Analysis
New Idea Generation
Support for Data Mining & Analysis



Support for Data Mining & Analysis



- Statisticians
  - Analysis of outcomes and study
- Principal Investigator
  - Identification of new treatments or therapies
- Patients
  - Evaluate the success of treatments
    - Positive and negative studies
- Scientific abstraction
  - Stopping rules, efficacy
- State of the science meetings (CTEP)
- Raw data sharing
  - Aggregation, cross-study analysis capabilities
- HIPAA
  - Data ownership, privacy

Steps to take

- Define life-cycle of clinical trials data and applications
- Identify and prioritize life cycle activities for work tasks
- Scope high priority modeling efforts
- Get input from other protocol representation groups

Possible Statements of Work

- Identify strategic goals and scope the project. Articulate assumptions, definitions and constraints to a clinical trial protocol representation and tools to support it.
- Identify or Revise Stakeholders, Experts, and Other Sources of Requirements for clinical trial protocol representations (CTEP, HL7, caCORE, others)
  - Other SIGs
  - Other working groups
  - Cooperative groups (involved through cancer institutes, etc)
    - Contact: CTEP, CTSU
    - Mayo system integrates all clinical research into one system
  - AACI (Doug Stahl)
  - CTEP tool for protocol authoring
  - FDA protocol structure working group
  - Protocol registration clinical trials/ protocol (.gov)
  - Other sigs –integrative biology (data sharing)
  - SPORE HIPAA IRB,
  - Standards for biomarkers

Possible Statements of Work

- Gather User Requirements for the life cycle of clinical trial protocols
- Compare the user requirements to the business needs of the application. Identify gaps and resolve conflicts
- Conduct a formal Draft Requirements Specification Document Peer Review with working group colleagues

Possible Statements of Work

- Perform Requirements Scoping and develop a Release Plan.
- Prioritize requirements and create a plan that prioritizes the order in which the requirements will be developed and deployed

  What is the minimum dataset to do this?

- Develop Design Plan

Possible Statements of Work

- Walk a protocol through the system: evaluate adequacy of the system
- Pilot Evaluation: Identify a caBIG compliant component of the protocol authoring tool for evaluation and roll it out in at least two adopter sites.
  - Evaluate the UI, deployment and implementation strategies, and assess the interoperability of the system both within the two adopter sites, and how this generalizes to other cancer centers.
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Priorities

- What part(s) of the life-cycle should we focus on first?
  - CRC authoring?
    - Summary 4 structure
- What parts of the life-cycle should we coordinate with other SIGs or working groups?
  - Reporting
  - Financials
  - Integrative biology

Other notes/issues

- Can the NCI dictate that cooperative groups, SPOREs, etc, use caBIG compliant tools and representations?
- White paper from cooperative group that describes clinical trials
- NCI initiative on clinical trials (CTWG)
  - Need to get representation on this group from CT working group/sigs in caBIG
  - Strategic roadmap due next year
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